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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/559,825	12/02/2005	Rachel Schneerson	4239-68226-07	1579
36218	7590	04/03/2007	EXAMINER	
KLARQUIST SPARKMAN, LLP			SWARTZ, RODNEY P	
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SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		04/03/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/559,825	SCHNEERSON ET AL.	
	Examiner Rodney P. Swartz, Ph.D.	Art Unit 1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

1) Responsive to communication(s) filed on 2December 2005.  
 2a) This action is FINAL.                            2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

4) Claim(s) 1-6,8-22 and 34-46 is/are pending in the application.  
 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-6,8-22 and 34-46 is/are rejected.  
 7) Claim(s) 1,5 and 34 is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 2December 2005 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)	4) <input type="checkbox"/> Interview Summary (PTO-413)
2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Date. _____
3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date <u>12/05,11/06</u> .	5) <input type="checkbox"/> Notice of Informal Patent Application
	6) <input type="checkbox"/> Other: _____.

### **DETAILED ACTION**

1. Applicants' Preliminary Amendment, received 2 December 2005, is acknowledged. Claims 1, 2, 8-14, and 16 have been amended. Claims 7 and 23-33 have been canceled. New claims 34-46 have been added.
2. Claims 1-6, 8-22, and 34-46 are pending and under consideration.

### **Specification**

3. The disclosure is objected to because of the following informalities:

Page 37, line 14, "pre chain" should be "per chain".

Page 46, line 19, "V. cholerae" should be in italics.

Appropriate correction is required.

### **Claim Objections**

4. Claim 1 is objected to because of the following informality: lines 1-2, "comprising a a synthetic" should be "comprising a synthetic". Appropriate correction is required.
5. Claim 5 is objected to because of the following informality: line 6, the group of analogs or mimetics should be group (o) and combinations should be group (p) for consistency of the listing. Appropriate correction is required.
6. Claim 34 is objected to because of the following informality: line 7, the group of analogs or mimetics should be group (m) and combinations should be group (n) for consistency of the listing. Appropriate correction is required.

### **Claim Rejections - 35 USC § 112**

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 5 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the Markush group listing in Claim 5, the Markush group recites (a) - bovine serum albumin, and later, (m) - mammalian serum albumins. It is unclear what the distinction is here.

9. Claims 16-22 and 42-46 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 16, 18, and 42 are directed to a composition comprising the conjugate of claim 1 (homopolymer polypeptide of  $\gamma$ PGA covalently linked to a carrier) and a pharmaceutically acceptable carrier. It is unclear if the carrier of the composition is the same or different than the carrier covalently linked to  $\gamma$ PGA. Claims 17, 19-22, and 43-46 depend from these claims, but do not clarify the indefiniteness.

10. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a conjugate wherein the  $\gamma$ PGA "comprises" the D- or L-conformation. It is unclear what is meant by this phrase. Is the  $\gamma$ PGA one of the conformational forms or is the conjugate made up of both conformational forms.

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11. Claim 9 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a conjugate wherein the  $\gamma$ PGA "comprises"  $\gamma$ DPGA. It is unclear from this phrase if the  $\gamma$ PGA is only the  $\gamma$ DPGA or may also include other conformational forms.

12. Claim 10 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a conjugate wherein the  $\gamma$ PGA polypeptide "comprises" a decameric  $\gamma$ DPGA. It is unclear from this phrase if the  $\gamma$ PGA is only the decameric  $\gamma$ DPGA or may also include other polymeric and conformational forms.

13. Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a conjugate wherein the  $\gamma$ PGA "comprises" the D- or L-conformation. It is unclear what is meant by this phrase. Is the  $\gamma$ PGA one of the conformational forms or is the conjugate made up of both conformational forms.

14. Claim 38 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The claim is drawn to a conjugate wherein the  $\gamma$ PGA "comprises"  $\gamma$ DPGA. It is unclear from this phrase if the  $\gamma$ PGA is only the  $\gamma$ DPGA or may also include other conformational forms.

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15. Claims 5 and 34-44 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for immunogenic conjugates comprising homopolymer polypeptides of  $\gamma$ PGA covalently linked to a carrier wherein the carrier is a specific protein, does not reasonably provide enablement for immunogenic conjugates comprising homopolymer polypeptides of  $\gamma$ PGA covalently linked to a carrier wherein the carrier is an analog or mimetic of the specific protein. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

The nature of the invention - immunogenic conjugates comprising homopolymer polypeptides of  $\gamma$ PGA covalently linked to a carrier wherein the carrier is an analog or mimetic of the specific protein.

The state of the prior art concerning analogs and mimetics is evidenced by applicants' definitions of the terms in the instant specification, page 4, line 16-24. An analog is defined as "a molecule that differ in chemical structure from a parent compound". However, applicants' definition does not require any similarity in activity with the parent compound. A mimetic is defined as "a molecule that mimics the activity of another molecule". However, the rest of the

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specification does not define which activities of the parent compound are to be mimiced. Therefore, based upon applicants' definitions, and a lack of sufficient guidance or working examples, the extremely broad scope of the claims constitute merely an invitation to experiment to determine what "analogs" or "mimetics" are to be included or excluded from the instant scope of the claims.

**Claim Rejections - 35 USC § 102**

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

17. Claim 34-38 are rejected under 35 U.S.C. 102(b) as being anticipated by Alkan et al (*J. Immunology*, 107(2):353-358, 1971).

The claims are drawn to a conjugate comprising a *Bacillus* capsular  $\gamma$ PGA linked to a carrier wherein said carrier is an analog or mimetic of a list of proteins. An analog is defined as "a molecule that differ in chemical structure from a parent compound", and a mimetic is defined as "a molecule that mimics the activity of another molecule". (page 4, lines 16-24 of specification).

Alkan et al teach the claimed conjugates comprising a *Bacillus* capsular  $\gamma$ PGA linked to RAT, which by applicants' definitions, is an analog and a mimetic of the listed proteins (Abstract, page 354, second column, second paragraph).

**Claim Rejections - 35 USC § 103**

18. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

19. Claims 1-6, 8, 9, and 11-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alkan et al (*J. Immunology*, 107(2):353-358, 1971) and Welkos et al (*Microbiol.*, 147:1677-1685, 2001) in view of Pozsgay et al (*Proc. Natl. Acad. Sci., USA*, 96:5194-5197, 1999).

The claims are drawn to a conjugate comprising a homopolymer polypeptide of capsular  $\gamma$ PGA linked to a carrier, wherein said carrier may be an analog or mimetic of a list of proteins. An analog is defined as "a molecule that differ in chemical structure from a parent compound", and a mimetic is defined as "a molecule that mimics the activity of another molecule". (page 4, lines 16-24 of specification).

Alkan et al teach the claimed conjugates comprising a *Bacillus* capsular  $\gamma$ PGA linked to RAT, which by applicants' definitions, is an analog and a mimetic of the listed proteins (Abstract, page 354, second column, second paragraph). Alkan et al do not teach homopolymers of the  $\gamma$ PGA.

Welkos et al teach that *B. anthracis* protective antigen and  $\gamma$ DPGA result in antibody production following vaccination and that improved vaccines could therefore contain these multiple antigenic moieties (Abstract; discussion, pages 1683-1684).

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Pozsgay et al do teach that synthetic polymers of hapten moieties determines optimal immunogenicity for conjugates composed of linear polymers bound to a carrier protein (abstract; Methods section, page 5195; Table 2).

Thus, it would have been obvious to one skilled in the art to adapt the teachings of Pozsgay et al concerning polymeric forms of haptenic molecules to increase the immunogenicity of the conjugates of Alkan et al and couple the conjugates with multiple antigens, such as taught by Welkos et al, in order to maximize any anti-*Bacillus* responses.

### Conclusion

20. No claims are allowed.
21. Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rodney P. Swartz, Ph.D., Art Unit 1645, whose telephone number is (571) 272-0865. The examiner can normally be reached on Monday through Thursday from 9:00 AM to 7:30 PM EST.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Jeffrey Siew, can be reached on (571)272-0787.

The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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RODNEY P SWARTZ, PH.D  
PRIMARY EXAMINER

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March 28, 2007